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Registration Decision RD2013-06

Proxitane

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Registration Decision for Proxitane

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Proxitane and Proxitane WW-12, containing the technical grade active ingredient proxitane, to control bacteria in municipal sewage and wastewater effluent.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2012-28, *Proxitane*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for proxitane and summarizes the Agency's decision, the reasons for it. The PMRA received no comments on PRD2012-28. This decision is consistent with the proposed registration decision stated in PRD2012-28.

For more details on the information presented in this Registration Decision, please refer to PRD2012-28, *Proxitane*, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's *(a)* efficacy; *(b)* effect on host organisms in connection with which it is intended to be used; and *(c)* health, safety and environmental benefits and social and economic impact".

reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is Proxitane?

The technical active Proxitane consists of the active ingredients hydrogen peroxide and peroxyacetic acid. The two active ingredients are mixed and form an aqueous equilibrium solution consisting of acetic acid, peroxyacetic acid, hydrogen peroxide and other inert ingredients. This aqueous solution is known to kill cells by oxidizing cellular macromolecules including lipids, proteins and nucleic acids. The final solution, of the end-use product Proxitane WW-12 that is applied to the effluent water is generated on site through a dispensing device.

Health Considerations

Can Approved Uses of Proxitane Affect Human Health?

Proxitane is unlikely to affect human health when it is used according to label directions.

Exposure to Proxitane may occur when handling the end-use product Proxitane WW-12, which has a proposed commercial use as an antimicrobial product intended for municipal wastewater disinfection. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, Proxitane, [hydrogen peroxide (20% w/w) and peroxyacetic acid (12.0% w/w)] is considered to be highly acutely toxic by the oral route, slightly acutely toxic by the dermal route, and moderately acutely toxic by the inhalation route. It is corrosive to both skin and eyes, and is not a dermal sensitizer. Signal words and cautionary statements alerting users to the potential for oral and inhalation toxicity, as well as corrosivity to skin and eyes, are required on both the technical grade active ingredient and end-use product labels.

Dermal or inhalation exposure is possible for workers handling the end-use product Proxitane WW-12, and for workers engaged in postapplication activities, such as coupling or uncoupling transfer lines. Therefore, precautionary measures including personal protective equipment are required on the end-use product label to mitigate such exposure concerns. The potential for bystander exposure is expected to be minimal as non-workers are not expected to be present in the wastewater treatment plant, and the end-use product is to be used in a closed system.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Due to the rapid decomposition of hydrogen peroxide and peroxyacetic acid to water and oxygen upon contact with moisture, and as Proxitane WW-12 is proposed for use as an antimicrobial product for municipal wastewater disinfection, no exposure via food or drinking water is expected to occur.

Occupational Risks From Handling Proxitane WW-12

Occupational risks are not of concern when Proxitane WW-12 is used according to label directions, which include protective measures.

Occupational exposure to individuals handling Proxitane WW-12 is not expected to result in unacceptable risk when the product is used according to label directions. Precautionary (for example, wearing of personal protective equipment) and hygiene statements on the label aimed at mitigating exposure are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What happens when Proxitane (containing the active ingredients peroxyacetic acid and hydrogen peroxide), as part of the end-use product Proxitane WW-12, is introduced into the environment?

Proxitane is a microbicide injected into municipal waste water just prior to release into the environment. Once in water, the active ingredients are rapidly hydrolyzed and spontaneously decomposed to acetic acid, water and oxygen. In addition, effluent will readily mix with receiving water, diluting the initial concentration found at the point of injection. Therefore, the concentrations of peroxyacetic acid and hydrogen peroxide in the effluents would be expected to be much reduced within a relatively short period after discharge. Peroxyacetic acid can be toxic to some aquatic organisms; however, based on the rapid degradation and dilution of the active ingredients once in the receiving environment, the use of the end-use product Proxitane WW-12 is expected to pose minimal risk to non-target aquatic organisms.

Value Considerations

What Is the Value of Proxitane WW-12?

Proxitane WW-12 is used for the control of bacteria in municipal sewage and wastewater effluent.

Proxitane WW-12 will provide active ingredients for reducing the number of bacteria in municipal wastewater effluents. This product will provide a new option for the chemical treatment of municipal wastewater as the currently available methods for this type of treatment

are limited, especially in Québec, where chlorine treatment is no longer permitted. Furthermore, the use of peroxyacetic acid does not lead to the formation of toxic chlorinated disinfection by-products in the effluent as chlorine does. The use of Proxitane WW-12 will provide a tool to meet fecal coliforms discharge limits.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures on the label of Proxitane WW-12 to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

The signal words 'DANGER – POISON, CORROSIVE TO EYES AND SKIN' are required on both the principal display panel of the technical grade active ingredient and end-use product labels. The statements 'Fatal or poisonous if swallowed', 'May be harmful if absorbed through the skin', 'May be fatal if inhaled', 'Corrosive to the eye and skin', 'Do not get in eyes or on skin' are required on the secondary display panel of both the technical grade active ingredient and end-use product labels.

Environment

A label statement is required indicating toxicity to aquatic organisms. However, based on the limited exposure and minimal risk to aquatic organisms under the specific use of this product, no risk reduction measures are required.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-28) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

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[5] *As per subsection 35(1) of the Pest Control Products Act.*